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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,889	09/04/2003	Richard A. Schmidt	5662-1-PUS-1-1	7191
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SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			EXAMINER AFREMOVA, VERA	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 02/14/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/655,889

Applicant(s)

SCHMIDT, RICHARD A.

Examiner

Vera Afrémova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/26/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 5, 9-11, 15 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 9, 10, 11, 15 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 4, 5, 9, 10, 11, 15 and 18-21 as amended (11/26/2007) are pending and under examination.

Claim Rejections - 35 USC § 112

Indefinite

Claims 1, 4, 5, 9, 10, 11, 15 and 18-21 as amended remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claimed invention is uncertain, unclear and indefinite with regard to its scope. Claims 1 and 10 recite “a patient with prostate cancer” under treatment with a botulinum toxin and, thus, the claimed invention is drawn to treating of prostate cancer. On the other hand, claims 1 and 10 recite “alleviating a symptom” and, thus, the claimed method appears to be irrelevant to treatment of prostate cancer because symptoms do not cause of a disease including cancer and because patients having the claimed symptoms do not necessarily have prostate cancer. The claimed symptoms are also manifestations of various different urological diseases that are distinct from prostate cancer. The state of the art indicates that prostate cancer does not cause symptoms until later in the disease when cure is less likely, for example: see the IDS reference by Crawford at page 3/6 par. 5.

The claimed invention is further failing to particularly point out and distinctly claim what for “a therapeutic amount of a botulinum toxin” is intended in the presently claimed method. If the therapeutic amount is intended to alleviate one or all of the claimed symptoms, the claimed limitation “prostate cancer patient” would have neither weight nor meaning. However, the

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claimed invention requires a patient with prostate cancer, and, thus, the claimed is directed to treating prostate cancer.

Therefore, the claimed invention is indefinite for being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

Enablement

Claims 1, 4, 5, 9, 10, 11, 15 and 18-21 as amended remain/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as explained in the prior office action and repeated herein.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The nature of the invention relates to method for treating neuronally-mediated urologic disorders with a botulinum toxin (specification page 1, lines 13-15). The specification disclosure provides a generic list of various neuronally-mediated urologic disorders including prostatic

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enlargement, pelvic pain, urinary incontinence, urinary retention, urge-type dysfunction, unstable bladder, unstable sphincter and recurrent urinary infection (specification pages 1-2). The generic disclosure says that prostate cancer is regarded as being related to the neuronally-mediated urologic disorders (specification page 1, lines 13-15) in a sense that treatment of prostate cancer with radiotherapy may have significant side effects such as neuronally-mediated urologic dysfunctions including bladder irritation, pain and urgency (specification page 6, par. 2).

The claimed invention encompasses administration of a botulinum toxin to a patient with prostate cancer. The history of patient(s) is not specified. Thus, the breadth of the claims is directed to a treatment of a prostate cancer patient by administration of botulinum toxin to the patient with prostate cancer.

As related to prostate cancer treatment it is known that prostate cancer is treated with surgery, radiation and/or hormone therapy (IDS reference by E. D. Crawford, page 4 of 6). The claimed therapeutic agent botulinum toxin acts as blocker of acetylcholine release from nerve endings and, accordingly, it blocks neural transmission when injected. (IDS reference by Leippold et al. [European Urology. 2003, 44:165-174] at page 166, col. 1, par. 3). Thus, treatment or cure of prostate cancer with botulinum toxin is at the very least unpredictable because prostate cancer is not a neurological disorder. Further, the instant specification does not provide examples of treating prostate cancer or curing prostate cancer as disclosed. Therefore, neither specification nor the prior art can be said to support the enablement of the claims over their breath. Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and

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limited number of working examples in the specification, the nature of the invention, the state of the art, breadth of the claims and the unpredictability of the art.

As related to the scope of claims drawn to administration of botulinum toxin to a patient with prostate cancer for alleviating symptoms of prostate cancer, the specification of the instant CIP application provides 3 new prophetic examples. In the examples 7-9 (pages 18-19) patients diagnosed with prostate cancer receive injections of botulinum toxin A. However, the actual results of botulinum administration to the patients with prostate cancer are not disclosed. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention because botulinum toxin primary affects neurological dysfunction but not prostate cancer. In the specification there is a single disclosure about one 65 year old patient with “disabling perineal pain following radiation treatment for prostatic cancer” who “experienced dramatic relief of testical pain” after botulinum injection. However, due to the age of patient and the complexity of his condition and treatments, the expectation that the “pelvic pain” would be relieved for any and all prostate cancer patients as claimed would be unreasonable. The state of art teaches that “large controlled trials are absolutely required to establish the role of botulinum-A toxin injections in the fields of urology and neurology on evidence based medicine”, for example: see last paragraph of abstract of the reference by Leippold et al. (IDS reference; European Urology. 2003, 44:165-174). Thus, the applicant’s singular, narrow working embodiment cannot be said to support the enablement of the claims over their breadth. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention.

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Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the art, breadth of the claims and the unpredictability of the art.

Therefore, the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Arguments

Applicant's arguments filed 11/26/2007 have been fully considered but they are not persuasive.

With regard to claim rejection under 35 U.S.C. 112, second paragraph, (indefinite) applicant appears to argue (response page 4) that the claimed invention is not about a prostate cancer but about "alleviating symptoms". Yet, claims recite "a patient with prostate cancer" who manifests "symptom(s)". In alternative, all claimed symptoms are symptoms of various and complex different diseases conditions that do not solely result from prostate cancer. Thus, the claimed invention fails to point out what is the scope of invention. Moreover, the state of the art indicates that prostate cancer does not cause symptoms until later in the disease when cure is less likely, for example: see the IDS reference by Crawford at page 3/6 par. 5. Since the claimed invention recites "a patient with prostate cancer", the presently claimed method has been considered as drawn to treating prostate cancer.

With regard to the clarity of claimed limitation “a therapeutic amount of a botulinum toxin” applicant argues that the specification examples 2 and 3 provide definitions and/or guidance about “therapeutic” dosages. However, the example 2 describes treatment of rats that do not have prostate cancer and the example 3 describes a cancer patient with some “testicle pain” but not with the “pelvic pain” as recited in the instant claims. Thus, the purpose of the claimed therapy remains uncertain. Moreover, although claims might be read in the light of specification but the specification is not read into the claims. In the instant case, the claimed symptoms are not necessarily manifested by prostate cancer patients only. Furthermore, neither claims nor as-filed specification establish the link between neural activity and prostate cancer, thus, amounting to the uncertainty of the claims.

With regard to claim rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement applicant argues that the claimed invention is not intended for treatment of prostate cancer but for alleviation of symptoms of a prostate cancer. Yet, the instant claims clearly require recite a patient having a prostate cancer and, thus, the breath of the claims is directed to treatment of prostate cancer, thereby, alleviating symptoms associated with urological disorders and conditions. Although treatment of cancer might result in alleviating the presently claimed symptoms of urological disorders, the alleviation of these symptoms is neither a cure from cancer nor control over cancer. Thus, undue experimentation would be required to practice the presently claimed method directed to treatment of prostate cancer.

Applicant argues that the specification examples 2 and 3 provide a reasonable correlation between biological activity of botulinum and alleviating symptoms of prostate cancer because

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example 2 describes shrinkage of prostate volume in rats injected with varying amounts of botulinum toxin and because example 3 describes relief of pain in a patient with prostate cancer treated with 200 IU injection of botulinum toxin. However, the rats of the example 2 do not have prostate cancer and the prostate cancer patient of the example 3 is said to have some relief from "testicle pain" but not from "pelvic pain" as recited.

Therefore, the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Therefore, the instant claims are properly rejected under 35 U.S.C. 112, first paragraph.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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February 11, 2008

A handwritten signature in black ink, appearing to read 'V. Afremova', with a long horizontal flourish extending to the right.

VERA AFREMOVA

PRIMARY EXAMINER